

Remarks

Claims 1-11 were pending in the subject application. By this Amendment, claims 1, 3, 4, 5, 6, 7, 9 and 11 have been amended, claim 10 has been cancelled and new claims 12-14 have been added. Accordingly, claims 1-9 and 11-14 are currently before the Examiner. The undersigned avers that no new matter is introduced by this amendment. Favorable consideration and entry of the amendments presented herein are respectfully requested.

The amendments and claim cancellation set forth herein should not be taken to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

The subject invention provides a unique composition in the form of a shaped body. The composition is freeze-dried, which inherently provides an advantageous open matrix by removing solvent to leave the carbohydrate in space.

Claim 3 has been objected to due to informalities. By this amendment, the applicants have amended claim 3 to correct the spelling of "pollulan" to "pullulan." The applicants appreciate the Examiner's careful review of the claims.

Claims 1, 3, and 8 have been rejected under 35 U.S.C. §102(b) as being anticipated by Nakamura *et al.* (U.S. Patent 4,623,394). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous freeze-dried, open-matrix composition.

Please note that freeze drying is not disclosed by Nakamura. In fact, Nakamura, at column 1, teaches away from the preparation of rapidly soluble matrices. Also, Examples 2 and 3 of Nakamura utilize conventional tableting techniques to prepare gradually-disintegrable articles. Such preparations will not comprise an open matrix when compared to one prepared by freeze-drying. Thus, the Nakamura compositions are readily distinguishable from those that are claimed in the current application.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Nakamura does not disclose or suggest the use of freeze drying or the preparation of a rapidly soluble open matrix as claimed by the current applicants. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Nakamura reference.

Claims 1, 3, 4, 6-8, and 11 have been rejected under 35 U.S.C. §102(b) as being anticipated by JP 08 291051. The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest a freeze-dried composition having the characteristics of the applicants' composition.

JP 08 291051 describes a method of production that utilizes a sequence of compression, humidification and drying. As opposed to being a compressed mass, the applicants respectfully submit that their claimed invention requires an "open matrix." Thus, the JP 08 291051 reference does not disclose or even suggest the subject invention because the cited reference uses compression and very minimum water such that there will be essentially no voids in the final product (the compressed mass).

Accordingly, the cited reference does not disclose each and every element of the claimed invention and the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the JP 08 291051 reference.

Claims 1, 4, and 6-10 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 91/09591. The applicants respectfully traverse this ground for rejection because the cited

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reference does not disclose or suggest a freeze-dried composition having the characteristics of the applicants' composition.

The cited reference merely uses solvent extraction to remove water and does not utilize freeze-drying as is recited in the applicants' claims. The applicants respectfully submit that each example from this reference to which the Office Action refers, describes how ice was dissolved in ethanol and subsequently transferred to a vacuum chamber to remove residual ethanol. Thus, the ice is removed by dissolution in a solvent and subsequent removal by evaporation in the cited reference as opposed to the sublimation of ice as occurs in freeze-drying.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the WO 91/09591.

Claims 1, 2, 4-7, 9, and 10 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 96/40077. The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants open-matrix, freeze-dried composition.

The cited reference teaches the formation of foamed, glass matrices via the evaporation of solvent under vacuum, without freezing. The applicants respectfully submit that this technique in the cited reference is not equivalent to the subject invention's freeze-drying process and would not produce a composition having the characteristics of the applicants' claimed composition. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the WO 96/40077.

Claims 1, 3, 4, and 6-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by Iwatsuki *et al.* (U.S. Patent 5,064,057). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest a freeze-dried composition having the characteristics of the applicants' composition.

The cited reference refers to pullulan in claim 7, but the product described does not have an "open matrix" since its methods of production include casting/drying, melting, and solidifying by cooling, moulding etc. The applicants respectfully traverse the Examiner's ground for rejection because such processes will not form a product constituting an open matrix.

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Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on Iwatsuki *et al.*

Claims 1, 2, and 4-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by Roser (U.S. Patent 5,704,297). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest a freeze-dried composition having the characteristics of the applicants' composition.

Roser teaches the production of dosage forms by a tableting process and subsequent removal of volatile salts under a vacuum. The applicants respectfully submit that their requirement that the composition be "freeze-dried" renders this citation no longer relevant. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Roser reference.

Hussain *et al.* (U. S. Patent 5,704,297) is cited of interest. Column 2 lines 50 to 53 indicate that an experiment was performed to assess the "feasibility of developing a dry powder formulation to improve the reconstitution rate of hydroxyethyl starch." Hence, the cited reference teaches away from the "shaped body" as claimed in the subject invention.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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